

IDS Form PTO/SB/08: Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

Application Number	10/721,020
Filing Date	November 25, 2003
First Named Inventor	Lukas-Laskey et al.
Art Unit	1614
Examiner Name	K. Weddington
Attorney Docket Number	04012.0385-00000

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
Examiner Initials	Cite No. ¹	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
KW		US-4,888,179	12-19-1989	APPLEGREN	
KW		US-5,312,828	05-17-1994	FINKEISTEIN	
KW		US-5,308,862	05-03-1994	OHLSTEIN	
KW		US-4,503,067	05-05-1985	WIEDEMANN	
KW		US-5,760,069	06-02-1998	LUKAS-LASKEY et al.	
KW		US-5,902,821	05-11-1999	LUKAS-LASKEY et al.	

Note: Copies of the U.S. Patent Documents are not Required in IDS filed after October 21, 2004

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
KW		CA 1,259,071	09-05-1989	BOEHRINGER MANNHEIM GMBH		
KW		EP 0 808 162 B1	11-26-1997	BOEHRINGER MANNHEIM PHARM CORP (US)		
KW		DE 696 02 424 T2	11-26-1997	BOEHRINGER MANNHEIM PHARM CORP (US)		Yes

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation ⁶

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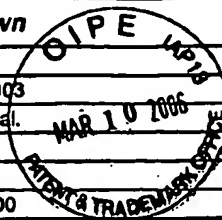
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Application Number 10/721,020
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KW	1	Bristol Meyers Squibb v. Ben Venue Labs., 246 F.3d 1368 (Fed. Cir. 2001).	
KW	2	Reoport v. Dement, 254 F.3d 1053 (Fed. Cir. 2001).	
KW	3	Jansen v. Rexall Sundown, Inc., 342 F.3d 1329, 1333-34 (Fed. Cir. 2003).	
KW	4	Glaxo Group Ltd. v. Teva Pharma, Inc., 2004 U.S. Dist. LEXIS 16750, at *56-57 (D. Del. 2004).	

Examiner
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		US-			
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KW		CLELAND et al., "Clinical trials update from the American College of Cardiology: darbepoetin alfa, ASTEROID, UNIVERSE, paediatric carvedilol, UNLOAD and ICELAND," European Journal of Heart Failure, 8, pp. 326-329, 2006.		
KW		SHADDY et al., "The pediatric randomized carvedilol trial in children with chronic heart failure: Rationale and design," American Heart Journal, vol. 144, no. 3, pp. 383-389, September 2002.		
KW		Summary Report, Study No.: SK&F-105517/321, "A Multicenter, placebo-controlled, 8-month study of the effect of twice daily carvedilol in children with congestive heart failure due to systemic ventricular systolic dysfunction," pp. 1-9, July 2006.		
KW		Clinical Study Report, Study No.: SK&F-105517/321, "A Multicenter, placebo-controlled, 8-month study of the effect of twice daily carvedilol in children with congestive heart failure due to systemic ventricular systolic dysfunction," abstract and cover pp. 1-4 and Clinical Study Report pp. 1-238, 266, 342-360, July 17, 2006		
KW		Summary Report, Study No.: SK&F-105517/396, "A Multicenter Open-label Extension Study to Evaluate the Safety of Twice Daily Oral Carvedilol in Pediatric Subjects with Chronic Heart Failure," abstract and cover pages pp. 1-4.		
KW		Clinical Study Report, Study No.: SK&F-105517/396, "A Multicenter Open-label Extension Study to Evaluate the Safety of Twice Daily Oral Carvedilol in Pediatric Subjects with Chronic Heart Failure," abstract and cover pages pp. 1-4 and Clinical Study Report pp. 1-135., August 2006.		
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				Art Unit	1614
Examiner Name	K. Weddington				
Sheet	1	of	24	Attorney Docket Number	04012.0385-00000

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Citation	Translation
KW	1.	Swedberg, Karl et al., "Prolongation of Survival in Congestive Cardiomyopathy by Beta-Receptor Blockade," Lancet 1374-1376 (June 30, 1979)	
KW	2.	Prichard, B.N.C. and Tomlinson, B., "Choice of Antihypertensive Drug Therapy," Am Heart J; 114 (4): 1030-40 (October 1987)	
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KW	15.	Feuerstein, G.Z. et al., "Myocardial protection with Carvedilol," J Cardiovasc Pharmacol, Vol. 19, Suppl. 1, pages S138-41 (1992)	
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KW	18.	Bristow, M.R., "Pathophysiologic and Pharmacologic Rationales for Clinical Management of Chronic Heart Failure with Beta-Blocking Agents," Am J Cardiol 71(9):12C-22C (1993)	
KW	19.	Cheng, H.-Y., et al., "Physical chemical investigation of antioxidant properties of carvedilol a cardioprotective drug," International Congress Series No. 1058, Frontiers of reactive oxygen species in biology and medicine, 349-350 (1994)	
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KW	21.	Fowler, M.B., "Controlled trials with beta blockers in heart failure: metoprolol as the prototype," Am J Cardiol Vol. 71, No. 9, pages 45C-53C (March 25, 1993)	
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KW	31.	Waagstein, Finn, "Beneficial Effects of metoprolol in idiopathic dilated cardiomyopathy," Lancet, Vol. 342. 1441-46 (December 11, 1993)	
KW	32.	Unknown, "SB to file seven NDAs, launch Havrix hepatitis A vaccine in 1995; No major drugs come off patent through 2000: Genomics work as synergy with diagnostics — BBS," F-C-D Reports — "The Pink Sheet", Vol. 56, No. 51, pages 17-18 (December 19, 1994)	
KW	33.	CIBIS Investigators and Committees, "A Randomized Trial of Beta-Blockade in Heart Failure — The Cardiac Insufficiency Bisoprolol Study (CIBIS)," Circulation, Vol. 90(4), 1765-1773 (1994)	
KW	34.	Doughty, R.N. et al., "Beta-Blockers in Heart Failure: Promising or Proved?" J Am Coll Cardiol 23(3):814-21 (1994)	
KW	35.	Hampton, J.R., "Choosing the right beta-blocker. A guide to selection," Drugs 48(4):549-68 (October 1994)	
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KW	45.	Unknown, "Smithkline Beecham/Boehringer Mannheim, UK/Germany: Carvedilol marketed," Bulletin International d'Informations (Droit et Pharmacie) No. 10, pages 82-83 (October 23, 1995)	Yes
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KW	47.	Unknown, "Boehringer Mannheim and SmithKline Beecham strengthen collaboration to market Carvedilol worldwide," Press Release, Page 1 (October 5, 1995)	
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KW	51.	Colucci, W.S. et al., "Carvedilol inhibits clinical progression in patients with mild heart failure — BIO," Circulation, Vol. 92, No. 9, Suppl., page I-395, Abstract 1884 (1995)	
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KW	64.	White, M. et al., "What patient with congestive heart failure respond to beta-blocking agents: A Meta-Analysis," Journal of Heart and Lung Transplantation Vol. 14, No. 1, page S85, Abstract 196 (1995)	
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KW	66.	Bonarjee, V.V. and Dickstein, K., "Novel drugs and current therapeutic approaches in the treatment of heart failure," Drugs 51(3):347-58 (March 1996)	
KW	67.	Dracup, K., "Heart failure secondary to left ventricular systolic dysfunction. Therapeutic advances and treatment recommendations," Nurse Pract 21(9):57,58,61,65-68 (September 1996)	
KW	68.	Feuerstein, G.Z. and Ruffolo, R.R., "Carvedilol, a novel vasodilating beta-blocker with the potential for cardiovascular organ protection," Eur Heart J 17 Suppl B:24-9 (April 1996)	
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KW	71.	Raflerty, E.B. "The preventative effects of vasodilating beta-blockers in cardiovascular disease," Eur Heart J 17 Suppl B:30-8 (April 1996)	
KW	72.	Sharpe, N., Beta-blockers in heart failure. Future directions, Eur Heart J 17 Suppl B:39-42 (April 1996)	
KW	73.	Beta-Blocker Evaluation of Survival Trial Investigators, "A Trial of the Beta-Blocker Bucindolol in Patients with Advanced Chronic Heart Failure," New England J. Med. 344(22), 1659-1667 (May 31, 2001)	
KW	74.	Ruffolo, R.R., et al., "Cardioprotective Potential of Carvedilol," Cardiology, 82(suppl 3), 24-28 (1993)	
KW	75.	Cohn, J.N., et al., "Effect of Vasodilator Therapy on Mortality in Chronic Congestive Heart Failure," New England J. Med, 314(24), 1547-52 (June 12, 1986)	
KW	76.	Whitfield, H.N., et al., "The effect of adrenergic blocking drugs on outflow resistance," Brit. J. Urology, 47, 823-827 (1976)	
KW	77.	Caine, M., et al., "The Use of Alpha-adrenergic blockers in Benign Prostatic Obstruction," Brit. J. Urology, 48, 255-263 (1976)	
KW	78.	Buchwald, A., et al., Z. Kardiolog, 79, 424-28 (1990)	English Abstract

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KW	79.	Tepper, D., "Multicenter Oral Carvedilol Heart Failure Assessment (MOCHA)," <i>Frontiers in CHF</i> , 2(1), 39-40 (1996)	
KW	80.	Waagstein, F., et al., "Effect of chronic beta-adrenergic receptor blockade in congestive cardiomyopathy," <i>Brit. Heart J.</i> , 37, 1022-36 (1975)	
KW	81.	Waagstein F. et al., "Beta-blockers in dilated cardiomyopathies: they work," <i>Eur. Heart J.</i> , 4(Supp A), 173-78 (1983)	
KW	82.	Novopharm, Notice of Allegation and Detailed Statement- Carvedilol 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg Tablets (Nov. 28, 2001)	
KW	83.	Notice of Application, Hoffmann-La Roche Ltd and Smithkline Beecham Corp. v. Minister of Health and Novopharm Ltd., Court No. T-84-02, Federal Court, Trial Division (Canada) (Jan. 16, 2002)	
KW	84.	Pharmascience, Notice of Allegation regarding carvedilol, 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg (August 30, 2001)	
KW	85.	Notice of Application, GlaxoSmithKline Inc. and SmithKline Beecham Corp. v. Minister of Health and Pharmascience Inc., Court No. T-1871-01, Federal Court, Trial Division (Canada) (October 18, 2001)	
KW	86.	Reasons for Order and Order, GlaxoSmithKline Inc. and SmithKline Beecham Corp. v. Minister of Health and Pharmascience Inc., Court No. T-1871-01, Federal Court, Trial Division (Canada) (July 18, 2003)	
KW	87.	Apotex Inc., Notice of Allegation in respect to Canadian Letters Patent No. 2,212,548 (June 19, 2003)	
KW	88.	Swedberg, K., et al., "Beneficial effects of long-term beta-blockade in congestive cardiomyopathy," <i>Brit Heart J.</i> , 44, 117-33 (1980)	
KW	89.	Swedberg, K., et al., "Adverse effects of beta-blockade withdrawal in patients with congestive cardiomyopathy," <i>Brit. Heart J.</i> , 44, 134-42 (1980)	
KW	90.	Drexler, H. et al., "Characterization of skeletal muscle β -adrenergic receptors in patients with chronic heart failure, <i>Circulation</i> 80(4), II-116 (1989)	
KW	91.	Diehm, C., Antihypertensive therapy in arterial occlusive disease, <i>Vasa Suppl</i> , 33, 71-4 (1991) (English language abstract only)	

Examiner Signature	/Kevin Weddington/ (03/20/2006)	Date Considered	
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				<i>First Named Inventor</i>	Lukas-Laskey et al.
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KW	92.	Sponer, G., et al., "Pharmacological profile of β -adrenoceptor blockers with vasodilating properties, especially Carvedilol - rationale for clinical use," Clin. Investig., 70, S20-S26 (1992)	
KW	93.	Lessem, J.N., Weber, M.A., "Antihypertensive treatment with a dual-acting beta-blocker in the elderly," J. Hypertens Suppl., 11(4), S29-36 (1993) (Abstract only)	
KW	94.	Olsen, S.L., et al., " β -Blocker related improvement in submaximal exercise tolerance in heart failure from idiopathic dilated cardiomyopathy (IDC)", JACC, 19, 146A, Abstract 747-5 (March 1, 1992)	
KW	95.	Harder S., et al., "Lack of pharmacokinetic interaction between carvedilol and digitoxin or phenprocoumon," Eur. J. Clin. Pharmacol., 44(6), 583-6 (1993) (Abstract only)	
KW	96.	Bristow, M.R., et al., "The β -blocking agents metoprolol and Carvedilol affect cardiac adrenergic drive differently in subjects with heart failure from idiopathic dilated cardiomyopathy," JACC, 21(2), 314A (Feb. 1993) (Abstract only)	
KW	97.	Australia/New Zealand Heart Failure Research Collaborative Group, "Randomised, placebo-controlled trial of Carvedilol in patients with congestive heart failure due to ischaemic heart disease," Lancet, 349, 375-80 (Feb. 8, 1997)	
KW	98.	Teva, Patent Certification Notice Letter re U.S. Patent Nos. 5,760,069 and 5,902,821 (May 24, 2002)	
KW	99.	Packer, M., "Effect of Carvedilol on Survival in Severe Chronic Heart Failure," New England J. Med., 344(22), 1651-1658 (May 31, 2001)	
KW	100.	Judgment, German Federal Republic Judgment nullity action 3 Ni 44/00 relating to DE 696 02 424 (EP 0 808 162), Egis Gyogyszergyar RT v. F. Hoffmann-La Roche AG (September 18, 2001) (English language translation)	
KW	101.	Defendant's Answer to Summons of July 6, 2001, German Federal Republic nullity action 3 Ni 44/00 relating to DE 696 02 424 (EP 0 808 162), Egis Gyogyszergyar RT v. Hoffmann-La Roche AG (August 23, 2001) (English language translation)	
KW	102.	Plaintiff's Brief, German Federal Republic nullity action 3 Ni 44/00 relating to DE 696 02 424 (EP 0 808 162), Egis Gyogyszergyar RT v. Boehringer Hoffmann-La Roche AG (August 7, 2001) (English language translation)	

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KW	103.	Substantiation of Opposition of Sept. 21, 2000, German Federal Republic nullity action 3 Ni 44/00 relating to DE 696 02 424 (EP 0 808 162), Egis Gyogyszergyar RT v. Boehringer Hoffmann-La Roche AG (Dec. 8, 2000) (English language translation)	
KW	104.	Nullification Petition, German Federal Republic nullity action relating to DE 696 02 424 (EP 0 808 162), Egis Gyogyszergyar RT v. Boehringer Hoffmann-La Roche AG (August 4, 2000) (English language translation)	
KW	105.	Judgment, German Federal Republic Judgment nullity action 3 Ni 57/91 relating to DE 36 12 537 (October 27, 1992) (English language translation)	
KW	106.	Ruling, German Federal Republic, Federal Patent Court, concerning Patent 22 23 237 (Jan. 13, 1989) (English Language Translation)	
KW	107.	Official Action, German Patent Office, Application No. P. 195 03 995.5-41 (August 17, 1995).	
KW	108.	Official Action, German Patent Office, Application No. P. 195 03 995.5-41 (November 7, 1995).	
KW	109.	Affidavit of Dr. William T. Abraham (March 8, 2002), filed in Hoffmann-La Roche Ltd and Smithkline Beecham Corp. v. Minister of Health and Novopharm Ltd., Court No. T-84-02, Federal Court, Trial Division (Canada), further including: <u>Exhibit A</u> : Curriculum Vitae of Dr. William T. Abraham, <u>Exhibit B</u> : Novopharm, Notice of Allegation and Detailed Statement- Carvedilol 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg Tablets (Nov. 28, 2001), <u>Exhibit C</u> : Canadian Patent Number 2,212,548, <u>Exhibit D</u> : Glossary of Terms, and <u>Exhibit E</u> : Commentary of Remaining Prior Art in Appendices A & B of the Novopharm Notice of Allegation.	
KW	110.	Affidavit of Dr. Mark Lautens (March 8, 2002), filed in Hoffmann-La Roche Ltd and Smithkline Beecham Corp. v. Minister of Health and Novopharm Ltd., Court No. T-84-02, Federal Court, Trial Division (Canada), further including: <u>Exhibit A</u> : Curriculum Vitae of Dr. Mark Lautens, <u>Exhibit B</u> : Novopharm, Notice of Allegation and Detailed Statement- Carvedilol 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg Tablets (Nov. 28, 2001), and <u>Exhibit C</u> : Canadian Patent Number 1,259,071.	

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KW	111.	<p>Affidavit of Edwin J. Gale (March 8, 2002), filed in Hoffmann-La Roche Ltd and Smithkline Beecham Corp. v. Minister of Health and Novopharm Ltd., Court No. T-84-02, Federal Court, Trial Division (Canada), further including:</p> <p><u>Exhibit A</u>: Canadian Patent Number 2,212,548,</p> <p><u>Exhibit B</u>: Novopharm, Notice of Allegation and Detailed Statement- Carvedilol 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg Tablets (Nov. 28, 2001),</p> <p><u>Exhibit C</u>: Chart of Claim Types and Allowability in Canada,</p> <p><u>Exhibit D</u>: Notice concerning acceptable claim types, Canadian Patent Office Record (May 9, 1989),</p> <p><u>Exhibit E</u>: Canadian Patent Office Manual of Patent Office Practice, §§ 11.10 - 11.10.02 (March 1998), and</p> <p><u>Exhibit F</u>: Chart of Claims of Canadian Patent Number 2,212,548, with claims grouped by type.</p>	
KW	112.	<p>Affidavit of Dr. Nadia S. Giannetti (March 8, 2002), filed in Hoffmann-La Roche Ltd and Smithkline Beecham Corp. v. Minister of Health and Novopharm Ltd., Court No. T-84-02, Federal Court, Trial Division (Canada), further including:</p> <p><u>Exhibit 1</u>: Curriculum Vitae of Dr. Nadia S. Giannetti,</p> <p><u>Exhibit 2</u>: Novopharm, Notice of Allegation and Detailed Statement- Carvedilol 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg Tablets (Nov. 28, 2001),</p> <p><u>Exhibit 3</u>: Canadian Patent Number 2,212,548,</p> <p><u>Exhibit 4</u>: Chart of Articles and Patents,</p> <p><u>Exhibit 5</u>: Letter of February 18, 2002, from Nika V. Ketis, Ph.D., LL.B. (Heenan Blaikie LLP) to Judith Robinson (Ogilvy Renault) regarding Case T-84-02.</p>	

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KW	113.	<p>Affidavit of Dr. John Parker (March 11, 2002), filed in Hoffmann-La Roche Ltd. and Smithkline Beecham Corp. v. Minister of Health and Novopharm Ltd., Court No. T-84-02, Federal Court, Trial Division (Canada), further including:</p> <p><u>Exhibit A</u>: Curriculum Vitae of Dr. John Parker,</p> <p><u>Exhibit B</u>: Novopharm, Notice of Allegation and Detailed Statement- Carvedilol 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg Tablets (Nov. 28, 2001),</p> <p><u>Exhibit C</u>: Canadian Patent Number 2,212,548,</p> <p><u>Exhibit D</u>: Glossary of Terms,</p> <p><u>Exhibit E</u>: Packer, M., et al., "The Effect of Carvedilol on Morbidity and Mortality in Patients with Chronic Heart Failure," New England J. Med. 334(21), 1349-1355 (May 23, 1996),</p> <p><u>Exhibit F</u>: Waagstein, F., "Beneficial Effects of Metoprolol in Idiopathic Dilated Cardiomyopathy," Lancet, 342, 1441-1446 (Dec. 11, 1993),</p> <p><u>Exhibit G</u>: CIBIS Investigators and Committees, "A Randomized Trial of β-Blockade in Heart Failure," Circulation, 90(4), 1765-1773 (Oct. 1994),</p> <p><u>Exhibit H</u>: Pfeffer, M.A., et al., "β-Adrenergic Blockers and Survival in Heart Failure," New England J. Med. 334(21), 1396-97 (May 23, 1996),</p> <p><u>Exhibit I</u>: Packer, M., "Effect of Carvedilol on Survival in Severe Chronic Heart Failure," New England J. Med., 344(22), 1651-1658 (May 31, 2001),</p> <p><u>Exhibit J</u>: Beta-Blocker Evaluation of Survival Trial Investigators, "A Trial of the Beta-Blocker Bucindolol in Patients with Advanced Chronic Heart Failure," New England J. Med. 344(22), 1659-1667 (May 31, 2001), and</p> <p><u>Exhibit K</u>: Commentary on Remaining Prior Art in Appendices A & B of the Novopharm Notice of Allegation.</p>	
KW	114.	<p>Affidavit of Dr. Ian Winterborn (March 11, 2002), filed in Hoffmann-La Roche Ltd and Smithkline Beecham Corp. v. Minister of Health and Novopharm Ltd., Court No. T-84-02, Federal Court, Trial Division (Canada), further including</p> <p><u>Exhibit A</u>: Curriculum Vitae for Dr. Ian Winterborn,</p> <p><u>Exhibit B</u>: Novopharm, Notice of Allegation and Detailed Statement- Carvedilol 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg Tablets (Nov. 28, 2001),</p> <p><u>Exhibit C</u>: Notice of Application, Hoffmann-La Roche Ltd and Smithkline Beecham Corp. v. Minister of Health and Novopharm Ltd., Court No. T-84-02, Federal Court, Trial Division (Canada) (Jan. 16, 2002),</p> <p><u>Exhibit D</u>: Canadian Patent Number 2,212,548,</p> <p><u>Exhibit E</u>: Canadian Patent Number 1,259,071,</p> <p><u>Exhibit F</u>: Canadian Patent Number 1,129,416, and</p> <p><u>Exhibit G</u>: United States Patent Number: 4,503,067.</p>	

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KW	115.	<p>Affidavit of Dr. Mary Ann Lukas (March 7, 2002), filed in Hoffmann-La Roche Ltd and Smithkline Beecham Corp. v. Minister of Health and Novopharm Ltd., Court No. T-84-02, Federal Court, Trial Division (Canada), further including:</p> <p><u>Exhibit A</u>: Curriculum Vitae for Dr. Mary Ann Lukas,</p> <p><u>Exhibit B</u>: Canadian Patent Number 2,212,548,</p> <p><u>Exhibit C</u>: German Patent Application No. 195 03 995.5 (PCT/EP 96/00498),</p> <p><u>Exhibit D</u>: English Translation of German Patent Application No. 195 03 995.5 (PCT/EP 96/00498),</p> <p><u>Exhibit E</u>: U.S. Patent Application Number 08/483,635,</p> <p><u>Exhibit F</u>: Novopharm, Notice of Allegation and Detailed Statement- Carvedilol 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg Tablets (Nov. 28, 2001),</p> <p><u>Exhibit G</u>: Loeg, H.S., et al., "Effect of Enalapril, Hyralazine Plus Isosorbide Dinitrate, and Prazonsin on Hospitalization in Patients with Chronic Congestive Heart Failure," Circulation 87(6), VI78 - VI87 (June 1993),</p> <p><u>Exhibit H</u>: DiBianco, R., et al., "A Comparison of Oral Milrinone, Digoxin, and Their Combination in the Treatment of Patients with Chronic Heart Failure," New England J. Med., 320(11), 677-683 (March 1989)</p> <p><u>Exhibit I</u>: Packer, M., et al., "Effect of Oral Milrinone on Mortality in Severe Chronic Heart Failure," New England J. Med. 325(21), 1468-75 (Nov. 21, 1991),</p> <p><u>Exhibit J</u>: Feldman, A.M., et al., "Effects of Vesnarinone on Morbidity and Mortality in Patients with Heart Failure," New England J. Med., 329(3), 149-155 (July 15, 1993)</p> <p><u>Exhibit K</u>: Kamoterol in severe heart failure study group, "Xamoterol in Severe Heart Failure," Lancet, 336, 1-6 (July 7, 1990),</p> <p><u>Exhibit L</u>: Waagstein, F., et al., "Beneficial Effects of Metoprolol in Idiopathic Dilated Cardiomyopathy," Lancet 342, 1441- 1446 (Dec. 11, 1993),</p> <p><u>Exhibit M</u>: CIBIS Investigators and Committees, "A Randomized Trial of β-Blockade in Heart Failure," Circulation, 90(4), 1765-1773 (Oct. 1994),</p> <p><u>Exhibit N</u>: Packer, M., et al., "The Effect of Carvedilol on Morbidity and Morality in Patients with Chronic Heart Failure," New England J. Med. 334(21), 1349-1355 (May 23, 1996),</p> <p><u>Exhibit O</u>: Pfeffer, M.A., et al., "β-Adrenergic Blockers and Survival in Heart Failure," New England J. Med. 334(21), 1396-97 (May 23, 1996),</p> <p><u>Exhibit P</u>: Packer, M., "Effect of Carvedilol on Survival in Severe Chronic Heart Failure," New England J. Med., 344(22), 1651-1658 (May 31, 2002), and</p> <p><u>Exhibit Q</u>: Commentary on Remaining Prior Art in Appendices A and B of the Novopharm Notice of Allegation.</p>	
	KW	116.	<p>Respondent's Record (Pharmascience Inc.) Volume I of III filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health, and Pharmascience Inc., Court File No. T-1871-01 (Canada), containing an index and:</p> <p><u>Exhibit A</u>: Exhibits to cross-examination of Dr. William T. Abraham taken on June 4, 2002. "77th Cardiovascular and Renal Drugs Advisory Committee meeting dated May 2, 1996," pp. 1-356.</p>

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KW	117.	Respondent's Record (Pharmascience Inc.) Volume II of III filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health and Pharmascience Inc., Court File No. T-1871-01 (Canada), containing an Index and: Continuation of <u>Exhibit A</u> to Dr. William T. Abraham's cross-examination (pp. 357-572) <u>Exhibit B</u> : Exhibits to cross-examination of Dr. Nadia S. Giannetti taken on June 21, 2002. "Study regarding sauna induced myocardial ischemia in patients with coronary artery disease," pp. 573-578. <u>Exhibit C</u> : Exhibits to cross-examination of Dr. Mary Ann Lukas taken on July 12, 2002. 1) Precise Trial Documentation, pp. 579-752 and 2) CPS Coreg Reference, pp. 753-756.	
KW	118.	Respondent's Record (Pharmascience Inc.) Volume III of III filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health and Pharmascience Inc., Court File No. T-1871-01 (Canada), containing an index and: <u>Exhibit D</u> : Memorandum of Fact and Law, pp. 757-802. Appendix A ("Anticipation by Kelly") to Respondent's Memorandum Fact and Law, pp. 788-801.	

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KW	119.	<p>Applicants' Record Volume 1 of 6 filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health and Pharmascience Inc., Court No. T-1871-00 (Canada), containing an Index and:</p> <p><u>Exhibit A</u>: Pharmascience Inc. Notice of Allegation dated August 30, 2001, pp. 1-11;</p> <p><u>Exhibit B</u>: Notice of Application issued October 18, 2001 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 12-27;</p> <p><u>Exhibit C</u>: Pharmascience Inc. Notice of Appearance dated October 26, 2001 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 28-31;</p> <p><u>Exhibit D</u>: Order of Prothonotary Lafrenière dated December 13, 2001 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 32-35;</p> <p><u>Exhibit E</u>: Order of Prothonotary Lafrenière dated March 7, 2002 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 36-39;</p> <p><u>Exhibit F</u>: Order of Prothonotary Lafrenière dated June 11, 2002 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 40-44;</p> <p><u>Exhibit G</u>: Confidentiality Order of Prothonotary Lafrenière dated August 2, 2002 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 45-55;</p> <p><u>Exhibit H</u>: Affidavit of Dr. William T. Abraham sworn January 29, 2002 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 56-96, further including: <u>Exhibit A</u>: <i>Curriculum vitae</i>, pp. 97-142; <u>Exhibit B</u>: Notice of Allegation, pp. 143-154; <u>Exhibit C</u>: Canadian Letters Patent No. 2,212,548, pp. 155-186; <u>Exhibit D</u>: Glossary of medical terms, pp. 187-193; <u>Exhibit E</u>: Further commentary on prior art, pp. 194-209;</p> <p><u>Exhibit I</u>: Transcript of cross-examination of Dr. Abraham taken on June 4, 2002 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 210-350, further including Exhibit 1 (Vogel et al., 24 Am. J. Cardiology 198-207 (1969)), Exhibit 2 (Bristow et al., 94 Circulation 2807-2816 (1996)), Exhibit 3 (Gilbert et al., 94 Circulation 2817-2825 (1996)), and Exhibit 4 (Shakar et al., 31 JACC 1336-1340 (1998));</p> <p><u>Exhibit J</u>: Affidavit of Dr. Nadia S. Giannetti sworn January 30, 2002 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 351-371, further including: Exhibit 1: <i>Curriculum vitae</i>, pp. 372-384; Exhibit 2: Notice of Allegation, pp. 385-396; Exhibit 3: Canadian Letters Patent No. 2,212,548, pp. 397-428; Exhibit 4: List of prior art referenced in Notice of Allegation, pp. 429-438;</p> <p><u>Exhibit K</u>: Transcript of cross-examination of Dr. Giannetti taken on June 21, 2002 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 439-529.</p>	
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KW	120.	Applicants' Record Volume 2 of 6 filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health and Pharmascience Inc., Court No. T-1871-00 (Canada), containing an Index and: <u>Exhibit L</u> : Affidavit of Patricia N. Jansons sworn January 24, 2002 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 530-540, further including: <u>Exhibit A</u> : Certified copy of Canadian Letters Patent No. 1,259,071, pp. 541-583; <u>Exhibit B</u> : Certified copy of the Abstract of Title for Canadian Letters Patent No. 1,259,071, pp. 584-585; <u>Exhibit C</u> : Certified copy of Canadian Letters Patent No. 2,212,548, pp. 586-617; <u>Exhibit D</u> : Certified copy of the Abstract of Title for Canadian Letters Patent No. 2,212,548, pp. 618-619; <u>Exhibit E</u> : Copy of CPS entry for COREG TM , pp. 620-625; <u>Exhibit F</u> : Copies of the 76 prior art references listed as paragraphs 1 to 13 and Appendix A of the Notice of Allegation (Tabs 1-46), pp. 626-1022.	
KW	121.	Applicants' Record Volume 3 of 6 filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health and Pharmascience Inc., Court No. T-1871-00 (Canada), containing an Index and: <u>Exhibit L</u> (cont.): <u>Exhibit F</u> : Copies of the 76 prior art references listed at paragraphs 1 to 13 and Appendix A of the Notice of Allegation (Tabs 47-76), pp. 1023-1186; <u>Exhibit M</u> : Affidavit of Dr. Mary Ann Lukas sworn January 30, 2002 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 1187-1212, further including: <u>Exhibit A</u> : <i>Curriculum vitae</i> , pp. 1214-1221, <u>Exhibit B</u> : Canadian Letters Patent No. 2,212,548, pp. 1222-1253; <u>Exhibit C</u> : German Patent Application No. 19503995.5 dated February 8, 1995, pp. 1254-1260; <u>Exhibit D</u> : English translation of German Application, pp. 1261-1267; <u>Exhibit E</u> : U.S. Patent Application No. 08/483,635 dated June 7, 1995, pp. 1268-1290; <u>Exhibit F</u> : Notice of Allegation, pp. 1291-1302; <u>Exhibit G</u> : Loeb publication, 1993, pp. 1303-1313; <u>Exhibit H</u> : DiBianco publication, 1989, pp. 1314-1321; <u>Exhibit I</u> : Packer publication, 1991, pp. 1322-1330; <u>Exhibit J</u> : Feldman publication, 1993, pp. 1331-1338; <u>Exhibit K</u> : Results of Xamoterol Trial, pp. 1339-1345; <u>Exhibit L</u> : Results of Metoprolol in Dilated Cardiomyopathy (MDC) Trial, pp. 1346-1352; <u>Exhibit M</u> : Results of the CIBIS I Trial, pp. 1353-1362; <u>Exhibit N</u> : Results of the U.S. Carvedilol Trials, pp. 1363-1370; <u>Exhibit O</u> : Pfeffer editorial on U.S. Carvedilol Trials, pp. 1371-1373; <u>Exhibit P</u> : Results of COPERNICUS Trial, pp. 1374-1382; <u>Exhibit Q</u> : Further commentary on prior art, pp. 1383-1393.	

Examiner Signature	/Kevin Weddington/ (03/20/2006)	Date Considered	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				<i>Application Number</i>	10/721,020
				<i>Filing Date</i>	November 25, 2003
				<i>First Named Inventor</i>	Lukas-Laskey et al.
				<i>Art Unit</i>	1614
				<i>Examiner Name</i>	K. Weddington
Sheet	15	of	24	<i>Attorney Docket Number</i>	04012.0385-00000

KW	122.	<p>Applicants' Record Volume 4 of 6 filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health and Pharmascience Inc., Court No. T-1871-00 (Canada), containing an Index and:</p> <p><u>Exhibit N</u>: Transcript of cross-examination of Dr. Lukas taken on July 12, 2002 (Canada, Federal Court-Trial Division, Court No. T-1871-01), pp. 1394-1795, further including Exhibit 1 (SmithKline Beecham Pharm., SK&F 105517/Carvedilol, protocol 220 (October 20, 1993), Exhibit 2 (SmithKline Beecham Pharm., SK&F 105517/Carvedilol, protocol 221 (October 20, 1993)), Exhibit 3 (SmithKline Beecham Pharm., SK&F 105517/Carvedilol, protocol 239 (June 9, 1994)), Exhibit 4 (SmithKline Beecham Pharm., SK&F 105517/Carvedilol, protocol 240 (January 25, 1994));</p> <p><u>Exhibit O</u>: Affidavit of Dr. John Parker sworn January 31, 2002 (Canada, Federal Court-Trial Division, Court No. T-1871-01), pp. 1796-1828, further including: <u>Exhibit A</u>: <i>Curriculum vitae</i>, pp. 1829-1851; <u>Exhibit B</u>: Notice of Allegation, pp. 1852-1863; <u>Exhibit C</u>: Canadian Letters Patent No. 2,212,548, pp. 1864-1896; <u>Exhibit D</u>: Glossary of medical terms, pp. 1897-1903; <u>Exhibit E</u>: Results of U.S. Carvedilol Trials, pp. 1904-1910; <u>Exhibit F</u>: Results of Metoprolol in Dilated Cardiomyopathy (MDS) Trials, pp. 1911-1917; <u>Exhibit G</u>: Results of CIBIS I Trial, pp. 1918-1927; <u>Exhibit H</u>: Pfeffer editorial on U.S. Carvedilol Trials, pp. 1928-1930; <u>Exhibit I</u>: Results of COPERNICUS Trial, pp. 1931-1939; <u>Exhibit J</u>: Results of BEST Trial, pp. 1940-1949; <u>Exhibit K</u>: Further commentary on prior art, pp. 1950-1959;</p> <p><u>Exhibit P</u>: Transcript of cross-examination of Dr. Parker taken on July 3, 2002, pp. 1960-2082.</p>	
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Examiner Signature	/Kevin Weddington/ (03/20/2006)	Date Considered	
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				<i>First Named Inventor</i>	Lukas-Laskey et al.
				<i>Art Unit</i>	1614
				<i>Examiner Name</i>	K. Weddington
Sheet	16	of	24	<i>Attorney Docket Number</i>	04012.0385-00000

KW	123.	<p>Applicants' Record Volume 5 of 6 filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health and Pharmascience Inc., Court No. T-1871-00, containing an Index and:</p> <p><u>Exhibit Q</u>: Affidavit of Dr. Bertram Pitt sworn April 1, 2002 (Canada, Federal Court-Trial Division, Court No. T-1871-01), pp. 2083-2121, further including <u>Exhibit A</u>: <i>Curriculum vitae</i>, pp. 2122-2193; <u>Exhibit B</u>: Comparison document prepared by Hitchman & Sprigings, pp. 2194-2209;</p> <p><u>Exhibit R</u>: Transcript of cross-examination of Dr. Pitt taken on June 24, 2002 (Canada, Federal Court-Trial Division, Court No. T-1871-01), pp. 2210-2284;</p> <p><u>Exhibit S</u>: Affidavit of Dr. Robert Rangno sworn April 1, 2002 (Canada, Federal Court-Trial Division, Court No. T-1871-01), pp. 2285-2324, further including Exhibit 1: <i>Curriculum vitae</i>, pp. 2325-2342; Exhibits 2-4 not included: Documents struck by Canadian Court order dated June 11, 2002</p> <p><u>Exhibit T</u>: Transcript of cross-examination of Dr. Rangno taken on June 26, 2002 (Canada, Federal Court-Trial Division, Court No. T-1871-01), pp. 2346-2411;</p> <p><u>Exhibit U</u>: Affidavit of Patrick Taylor sworn April 2, 2002 (Canada, Federal Court-Trial Division, Court No. T-1871-01), pp. 2412-2414, further including: <u>Exhibit A</u>: Product Monograph for COREG™ (carvedilol), pp. 2415-2419; <u>Exhibit B</u>: Further Detailed Information of the Prior Art References found in Appendix "A" to the Pharmascience Notice of Allegation, pp. 2420-2463; Exhibits C-F not included: Documents struck by Canadian Court order dated June 11, 2002;</p> <p><u>Exhibit V</u>: Affidavit of Dr. Lawrence Zisman sworn April 1, 2002 (Canada, Federal Court-Trial Division, Court No. T-1871-01), pp. 2469-2490, further including: <u>Exhibit A</u>: <i>Curriculum vitae</i>, pp. 2491-2504; <u>Exhibit B</u>: Comparison document prepared by Hitchman & Sprigings, pp. 2505-2521;</p> <p><u>Exhibit W</u>: Transcript of cross-examination of Dr. Zisman taken on July 10, 2002, pp. 2522-2592.</p>	
KW	124.	<p>Applicants' Record Volume 6 of 6 filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health and Pharmascience Inc., Court No. T-1871-00, further including:</p> <p><u>Exhibit X</u>: Written Representations, Applicants' Memorandum of Fact and Law, pp. 2593-2623.</p>	

Examiner Signature	/Kevin Weddington/ (03/20/2006)	Date Considered	
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				<i>First Named Inventor</i>	Lukas-Laskey et al.
				<i>Art Unit</i>	1614
				<i>Examiner Name</i>	K. Weddington
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KW	125.	<p>Affidavit of Edwin J. Gale, March 8, 2002, filed in Hoffmann-La Roche Limited, and Smithkline Beecham Corporation v. The Minister of Health, and Novopharm Limited, Court No. T-84-02, further including:</p> <p><u>Exhibit A</u>: Copy of Canadian Letters Patent No. 2,212,548;</p> <p><u>Exhibit B</u>: Notice of Allegation dated November 28, 2001 from Novapharm Limited to Hoffmann-La Roche;</p> <p><u>Exhibit C</u>: Chart of Edwin J. Gale illustrating various claim types used to cover pharmaceuticals including first and second medical uses and pharmaceuticals;</p> <p><u>Exhibit D</u>: Practice Notice regarding Chemical Patent Practice from the Canadian Patent Office Record of May 9, 1989;</p> <p><u>Exhibit E</u>: Copy of section on Method of Use and Use claims from the Canadian Manual of Patent Office Practice dated March 1998;</p> <p><u>Exhibit F</u>: Copy of Canadian Patent No. 2,212,548 claims grouped by type.</p>	
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				<i>First Named Inventor</i>	Lukas-Laskey et al.
				<i>Art Unit</i>	1614
				<i>Examiner Name</i>	K. Weddington
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KW	126.	<p>Applicants' Record filed in GlaxoSmithKline Inc. and Smithkline Beecham Corporation v. Apotex Inc. and The Minister of Health, Court File No. T-2105-02 (Canadian Federal Court-Trial Division), containing an Index and:</p> <p><u>Exhibit A</u>: Apotex Inc. Notice of Allegation dated November 1, 2003, pp. 1-2; <u>Exhibit B</u>: Notice of Application dated December 16, 2002, pp. 3-13; <u>Exhibit C</u>: Apotex Inc. Notice of Appearance dated December 20, 2002, pp. 14-16; <u>Exhibit D</u>: Minister of Health Notice of Appearance dated December 31, 2002, pp. 17-18; <u>Exhibit E</u>: Affidavit of Lidia O. Derewlany sworn on February 14, 2003, pp. 19-23, further including: Exhibit 1: Canadian Patent No. 2,212,548, pp. 24-54; Exhibit 2: Abstract of title for Canadian Patent No. 2,212,548, pp. 55-56; Exhibit 3: German Patent Application No. 19503995.5, pp. 57-63; Exhibit 4: English translation of German Patent Application No. 19503995.5, pp. 64-70; Exhibit 5: U.S. Patent Application No. 08/483,635, pp. 71-92; Exhibit 6: Notice of Compliance dated February 17, 1995 and approved product monograph for Kredex tablets, pp. 93-115; Exhibit 7: Cover page of the S/NDS dated December 13, 1995 for Coreg™ tablets (redacted), pp. 116-118; Exhibit 8: Correspondence from Viera Pastorek, Health Canada, dated January 10, 1996, pp. 119-121; Exhibit 9: Notice of Compliance dated September 30, 1996, pp. 122-160; Exhibit 10: Health Canada Patent Lists filed by Hoffmann-LaRoche for Coreg™ tablets, pp. 161-165; Exhibit 11: Cover page for the September 13, 2001 S/NDS filed by GlaxoSmithKline Inc., pp. 166-167; Exhibit 12: Correspondence from A. Minkiewicz-Janda dated October 29, 2001, pp. 168-171; Exhibit 13: Health Canada Patent Lists filed by GlaxoSmithKline Inc., pp. 172-176; Exhibit 14: Notice of Compliance dated April 10, 2002 and approved product monograph for Coreg™ tablets, pp. 177-227; <u>Exhibit F</u>: Transcript of cross-examination of Lidia O. Derewlany taken April 24, 2003, pp. 229-269; <u>Exhibit G</u>: Correspondence dated May 23, 2003 for Ogilvy Renault to Goodmans LLP, pp. 270-271; <u>Exhibit H</u>: Affidavit of Dianne Kathleen Grisé sworn on February 14, 2003, pp. 272-275; <u>Exhibit I</u>: Transcript of cross-examination of Dianne Kathleen Grisé taken May 6, 2003, pp. 276-312; <u>Exhibit J</u>: Affidavit of Bernard Sherman sworn on March 7, 2003, pp. 313-315; <u>Exhibit K</u>: Written Representations, memorandum of Fact and Law, of GlaxoSmithKline and SmithKline Beecham Corporation dated June 5, 2003, pp. 316-346.</p>	
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Examiner Signature	/Kevin Weddington/ (03/20/2006)	Date Considered	
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				<i>First Named Inventor</i>	Lukas-Laskey et al.
				<i>Art Unit</i>	1614
				<i>Examiner Name</i>	K. Weddington
Sheet	19	of	24	<i>Attorney Docket Number</i>	04012.0385-00000

KW	127.	<p>Applicants' Record, Volume 1 of 7, filed in Hoffmann-La Roche Limited and Smithkline Beecham Corporation v. The Minister of Health and Novopharm Limited, Court No. T-84-02 (Canadian Federal Court-Trial Division), containing an Index and:</p> <p><u>Exhibit A</u>: Novopharm Limited Notice of Allegation dated November 28, 2001, pp. 1-20; <u>Exhibit B</u>: Notice of Application issued January 16, 2002, pp. 21-36; <u>Exhibit C</u>: Novopharm Limited Notice of Appearance dated January 18, 2002, pp. 37-39; <u>Exhibit D</u>: Minister of Health Notice of Appearance dated January 24, 2002, pp. 40-41; <u>Exhibit E</u>: Order of Prothonotary Lafrenière dated February 11, 2002, pp. 42-44; <u>Exhibit F</u>: Confidentiality Order of Prothonotary Lafrenière dated February 11, 2002, pp. 45-52; <u>Exhibit G</u>: Correspondence dated February 18, 2002 from Heenan Blaikie, counsel for the Respondent, Novopharm Limited to Ogilvy Renault, counsel for the Applicants, pp. 53-55; <u>Exhibit H</u>: Order of Prothonotary Lafrenière dated November 4, 2002, pp. 56-57; <u>Exhibit I</u>: Correspondence dated January 27, 2003 from Heenan Blaikie, counsel for the Respondent, Novopharm Limited to Ogilvy Renault, counsel for the Applicants, pp. 53-57a; <u>Exhibit J</u>: Affidavit of Patrica N. Jansons sworn March 4, 2002, pp. 58-72, further including: <u>Exhibit A</u>: Certified copy of Canadian Letters Patent No. 1,259,071, pp. 73-115; <u>Exhibit B</u>: Certified copy of the Abstract of Title for Canadian Letters Patent No. 1,259,071, pp. 116-117; <u>Exhibit C</u>: Certified copy of Canadian Letters Patent No. 2,212,548, pp. 118-146; <u>Exhibit D</u>: Certified copy of the Abstract of Title for Canadian Letters Patent No. 2,212,548, pp. 147-148; <u>Exhibit E</u>: Copy of CPS entry for COREG™, pp. 149-154; <u>Exhibit F</u>: Copies of the 104 prior art references listed at page 5 & 6 and Appendix A & B of the Novopharm Notice of Allegation, pp. 155-534.</p>	
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Examiner Signature	/Kevin Weddington/ (03/20/2006)	Date Considered	
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				<i>First Named Inventor</i>	Lukas-Laskey et al.	
				<i>Art Unit</i>	1614	
				<i>Examiner Name</i>	K. Weddington	
Sheet	20	of	24	<i>Attorney Docket Number</i>		04012.0385-00000

KW	128.	<p>Applicants' Record, Volume 3 of 7, filed in Hoffmann-La Roche Limited, and Smithkline Beecham Corporation v. The Minister of Health and Novopharm Limited, Court No. T-84-02, further including:</p> <p><u>Exhibit K</u>: Affidavit of Dr. Mary Ann Lukas sworn March 7, 2002, pp. 1026-1059, further including: <u>Exhibit A</u>: Curriculum vitae, pp. 1060-1067; <u>Exhibit B</u>: Canadian Letters Patent No. 2,212,548, pp. 1068-1105; <u>Exhibit C</u>: German Patent Application No. 19503995.5 dated February 8, 1995, pp. 1106-1112; <u>Exhibit D</u>: English translation of German Application, pp. 1113-1119; <u>Exhibit E</u>: U.S. Patent Application No. 08/483,635 dated June 7, 1995, pp. 1120-1141; <u>Exhibit F</u>: Novopharm Notice of Allegation (Nov. 28, 2001), pp. 1142-1162; <u>Exhibit G</u>: Loeb et al., 87 Circulation VI-78 to VI-87 (1993), pp. 1163-1173; <u>Exhibit H</u>: DiBianco et al., 320 N.E.J. Med. 677-683 (1989), pp. 1174-1181; <u>Exhibit I</u>: Packer et al., 325 N.E.J. Med. 1468-1475 (1991), pp. 1182-1190; <u>Exhibit J</u>: Feldman et al., 329 N.E.J. Med. 149-155 (1993), 1191-1198; <u>Exhibit K</u>: Results of Xamoterol Trial, 336 Lancet 1-6 (1990), pp. 1199-1205; <u>Exhibit L</u>: Results of the Metoprolol in Dilated Cardiomyopathy (MDS) Trial, 342 Lancet 1441-46 (1993), pp. 1206-1212; <u>Exhibit M</u>: Results of the CIBIS I Trial, 90 Circulation 1765-1773 (1994), pp. 1213-1222; <u>Exhibit N</u>: Results of the U.S. Carvedilol Trials, 334 N.E.J. Med. 1349-1355, pp. 1223-1230; <u>Exhibit O</u>: Pfeffer editorial on U.S. Carvedilol Trials 334 N.E.J. Med. 1396-1397, pp. 1231-1233; <u>Exhibit P</u>: Results of COPERNICUS Trial, 344 N.E.J. Med. 1651-1658, pp. 1234-1242; <u>Exhibit Q</u>: Further commentary on prior art, pp. 1243-1256; <u>Exhibit L</u>: Transcript of cross-examination of Dr. Lukas taken on January 28, 2003, pp. 1257-1333;</p> <p><u>Exhibit M</u>: Affidavit of Dr. William T. Abraham sworn March 8, 2002, pp. 1334-1382, further including: <u>Exhibit A</u>: Curriculum vitae, pp. 1383-1428; <u>Exhibit B</u>: Notice of Allegation (pp. 3-19), pp. 1429-1449; <u>Exhibit C</u>: Canadian Letters Patent No. 2,212,548, pp. 1450-1481; <u>Exhibit D</u>: Glossary of medical terms, pp. 1482-1488, <u>Exhibit E</u>: Further commentary on prior art, pp. 1489-1506;</p> <p><u>Exhibit N</u>: Transcript of cross-examination of Dr. Abraham taken on November 26, 2002, pp. 1507-1628, further including: Exhibit 1: Abraham et al., 39 Advances in Internal Medicine, 22-47 (1994); Exhibit 2: Results of CONSENSUS Trial, 316 N.E.J. Med. 1429-1435 (1987); Exhibit 3: Bristow et al., 94 Circulation, 2807-16 (1996); Exhibit 4: Shaker et al., 31 JACC 1336-1340 (1998), Exhibit 5: Gilbert et al., 94 Circulation 2817-25 (1996); Exhibit 6: Abraham et al., 22 Hepatology, 737-743 (1995).</p>	
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Examiner Signature	/Kevin Weddington/ (03/20/2006)	Date Considered	
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				<i>Art Unit</i>	1614
				<i>Examiner Name</i>	K. Weddington
Sheet	21	of	24	<i>Attorney Docket Number</i>	04012.0385-00000

KW	129.	<p>Applicants' Record, Volume 4 of 7, filed in Hoffmann-La Roche Limited, and Smithkline Beecham Corporation v. The Minister of Health, and Novopharm Limited, Court No. T-84-02, containing an Index and:</p> <p><u>Exhibit Q</u>: Affidavit of Dr. Nadia S. Giannetti sworn March 8, 2002, pp. 1629-1656, further including Exhibit 1: <i>Curriculum vitae</i>, pp. 1657-1669; Exhibit 2: Novopharm Notice of Allegation (Nov. 28, 2001), pp. 1670-1690; Exhibit 3: Canadian Letters Patent No. 2,212,548, pp. 1691-1723; Exhibit 4: List of prior art referenced in Notice of Allegation, pp. 1724-1737; Exhibit 5: Correspondence from Heenan Blaikie to Ogilvy Renault dated February 18, 2002, pp. 1739-1742;</p> <p><u>Exhibit P</u>: Transcript of cross-examination of Dr. Giannetti taken on December 20, 2002, pp. 1743-1842, further including Exhibit 1: Johnstone et al., 10 Can. J. Cardiol 613-631 (1994); Exhibit 2: Giannetti et al., 107 Am. J. Med., 228-233 (1999); Exhibit 3: Cecere et al., Can J Cardiol, Vol. 17, Supp C, Abstract 272 (Sept. 2001); Exhibit 4: Cecere et al., Can J Cardiol, Vol. 17, Supp C, Abstract 376 (Sept. 2001); Exhibit 5: Cantarovich et al., J. Heart Lung Trans, Vol 20(2), Abstract 246 (2001); Exhibit 6: Cantarovich et al., J. Heart Lung Trans, Vol 20(2), Abstract 166 (2001);</p> <p><u>Exhibit Q</u>: Affidavit of Dr. Mark Lautens sworn March 8, 2002, pp. 1843-1847, further including <u>Exhibit A</u>: <i>Curriculum vitae</i>, pp. 1848-1877; <u>Exhibit B</u>: Novopharm Notice of Allegation (Nov. 28, 2001), pp. 1878-1898; <u>Exhibit C</u>: Canadian Letters Patent No. 1,259,071, pp. 1899-1941;</p> <p><u>Exhibit R</u>: Affidavit of Edwin Gale sworn March 8, 2002, pp. 1942-1951, further including: <u>Exhibit A</u>: Copy of Canadian Letters Patent No. 2,212,548, pp. 1952-1983; <u>Exhibit B</u>: Novopharm Notice of Allegation (Nov. 28, 2001), pp. 1984-2004; <u>Exhibit C</u>: Chart illustrating various claim types used to cover pharmaceuticals, pp. 2005-2006; <u>Exhibit D</u>: Practice Notice regarding Chemical Patent Practice taken from the Canadian Patent Office Record of May 9, 1989, pp. 2007-2008; <u>Exhibit E</u>: Section 11.10.02 entitled "Method of Use and Use Claims" from the Canadian Manual of Patent Office Practice, pp. 2009-2013; <u>Exhibit F</u>: Canadian Letters Patent No. 2,212,548 claims grouped by type, pp. 2014-2015.</p>	
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				<i>Examiner Name</i>	K. Weddington	
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KW	130.	<p>Applicants' Record, Volume 5 of 7, filed in Hoffmann-La Roche Limited, and Smithkline Beecham Corporation v. The Minister of Health, and Novopharm Limited, Court No. T-84-02, containing an Index and:</p> <p><u>Exhibit S</u>: Affidavit of Dr. John Parker sworn March 11, 2002, pp. 2016-2054, further including: <u>Exhibit A</u>: Curriculum vitae, pp. 2055-2077; <u>Exhibit B</u>: Notice of Allegation, pp. 2078-2098; <u>Exhibit C</u>: Canadian Letters Patent No. 2,212,548, pp. 2099-2130; <u>Exhibit D</u>: Glossary of medical terms, pp. 2131-2137; <u>Exhibit E</u>: Packer et al., 334 N.E.J. Med. 1349-1355 (1996), pp. 2138-2145; <u>Exhibit F</u>: Results of the Metoprolol in Dilated Cardiomyopathy (MDC) Trial 342 Lancet 1441-1446 (1993), pp. 2146-2152; <u>Exhibit G</u>: Results of CIBIS I Trial 90 Circulation, 1765-1773 (1994), pp. 2153-2162; <u>Exhibit H</u>: Pfeffer editorial on U.S. Carvedilol Trials, 334 N.E.J. Med. 1396-1397 (1996), pp. 2163-2165; <u>Exhibit I</u>: Results of COPERNICUS Trial, 344 N.E.J. Med. 1651-1658 (2001), pp. 2166-2174; <u>Exhibit J</u>: Results of BEST Trial, 334 N.E.J. Med. 1659-1667 (2001), pp. 2175-2184; <u>Exhibit K</u>: Further commentary on prior art, pp. 2185-2196;</p> <p><u>Exhibit T</u>: Transcript of cross-examination of Dr. Parker taken on December 18, 2002, pp. 2197-2364, further including Exhibit 1: Johnstone et al., 10 Can. J. Cardiol 613-631 (1994); Exhibit 2: Parker, 19 Eur. Heart J. Suppl. I 115-119 (1998); Exhibit 3: Rapaport et al., 101 Am. J. Med. 4A-61S-4A70S (1996); Exhibit 4: Al-Hesayen et al., 39 JACC 1269-1274 (2002); Exhibit 5: Azevedo et al., Circulation 2053-2056 (2000); Exhibit 6: Parker et al., 84 Circulation 1040-1048 (1991); Exhibit 7: Azevedo et al., 33 JACC 186-191 (1999); Exhibit 8: Azevedo et al., Circulation 274-279 (1999);</p> <p><u>Exhibit U</u>: Affidavit of Dr. Ian Winterborn sworn March 11, 2002, pp. 2365-2380, further including: <u>Exhibit A</u>: Curriculum vitae, pp. 2381-2385; <u>Exhibit B</u>: Notice of Allegation (Nov. 28, 2001), pp. 2386-2406; <u>Exhibit C</u>: Notice of Application, pp. 2407-2423; <u>Exhibit D</u>: Canadian Letters Patent No. 2,212,548, pp. 2424-2455; <u>Exhibit E</u>: Canadian Letters Patent No. 1,259,071, pp. 2456-2498; <u>Exhibit F</u>: Canadian Letters Patent No. 1,129,416, pp. 2499-2548; <u>Exhibit G</u>: United States Letters Patent No. 4,503,067, pp. 2549-2559.</p>	
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Examiner Signature	/Kevin Weddington/ (03/20/2006)	Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/721,020
				Filing Date	November 25, 2003
				First Named Inventor	Lukas-Laskey et al.
				Art Unit	1614
				Examiner Name	K. Weddington
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KW	131.	<p>Applicants' Record, Volume 6 of 7, filed in Hoffmann-La Roche Limited, and Smithkline Beecham Corporation v. The Minister of Health, and Novopharm Limited, Court No. T-84-02, containing an Index and:</p> <p><u>Exhibit V</u>: Affidavit of Dr. Mitchell Arnold Henry Levine sworn August 15, 2002, pp. 2560-2583, further including: <u>Exhibit A</u>: <i>Curriculum vitae</i>, pp. 2584-2614;</p> <p><u>Exhibit W</u>: Transcript of cross-examination of Dr. Mitchell Arnold Henry Levine taken on November 29, 2002, pp. 2615-2673, further including <u>Exhibit A</u>: Book entitled "Drugs of Choice: A Formulary for General Practice" (Canadian Medical Association: Toronto, 1995), pp. 2674-2849;</p> <p><u>Exhibit X</u>: Affidavit of Dr. Michael Bohm sworn August 16, 2002, pp. 2850-2875, further including <u>Exhibit A</u>: <i>Curriculum vitae</i>, pp. 2876-2980;</p> <p><u>Exhibit Y</u>: Transcript of cross-examination of Dr. Michael Bohm taken on December 9, 2002, pp. 2981-3028, further including: Exhibit 1: Article entitled "Different Intrinsic Activities of Bucidolol, Carvedilol and Metoprolol in Human Failing Myocardium," British Journal of Pharmacology (2000), 130, 1131-1139, pp. 3029-3037; Exhibit 2: Article entitled "Prospective Crossover Comparison of Carvedilol and Metoprolol in Patients with Chronic Heart Failure," American College of Cardiology, 38(4), 934-46 (2001), pp. 3038-3045; Exhibit 3: "β-Blocker Treatment of Chronic Heart Failure with Special Regard to Carvedilol" from book entitled "Heart Rate is a Determinant of Cardiac Function - Basic Mechanism and Clinical Significance," G. Hasenfuss et al. ed. (Steinkopff Verlag Darmstadt 2000) pp. 3046-3067.</p> <p><u>Exhibit Z</u>: Affidavit of Dr. Robert Rangno sworn August 20, 2002, pp. 3068-3094, further including <u>Exhibit A</u>: <i>Curriculum vitae</i>, pp. 3095-3102.</p> <p><u>Exhibit AA</u>: Transcript of cross-examination of Dr. Rangno taken on November 15, 2002, pp. 3103-3152.</p>	
KW	132.	<p>Affidavit of Dr. Mark Lautens filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health, and Apotex Inc., Court No. T-149-02, further including:</p> <p><u>Exhibit A</u>: <i>Curriculum vitae</i>;</p> <p><u>Exhibit B</u>: December 12, 2001 Notice of Allegation from Apotex Inc. to Smithkline Beecham Pharma Inc.;</p> <p><u>Exhibit C</u>: Canadian Letters Patent No. 1,259,071;</p>	
KW	133.	<p>Notice of Application filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health, and Apotex Inc., Court No. T-149-02.</p>	
KW	134.	<p>Record of the Respondent, Apotex Inc., filed in GlaxoSmithKline Inc. and Smithkline Beecham Corporation v. The Minister of Health and Apotex Inc., Court File No. T-149-02, further including:</p> <p>Exhibit 1: Memorandum of Fact and Law of the Respondent, Apotex Inc.</p>	

Examiner Signature	/Kevin Weddington/ (03/20/2006)	Date Considered	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				<i>Application Number</i>	10/721,020
				<i>Filing Date</i>	November 25, 2003
				<i>First Named Inventor</i>	Lukas-Laskey et al.
				<i>Art Unit</i>	1614
<i>Examiner Name</i>	K. Weddington				
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KW	135.	Reasons for Order and Order, filed in GlaxoSmithKline Inc. and Smithkline Beecham Corporation v. The Minister of Health and Pharmascience Inc., Court No. T-1871-01.	
KW	136.	Amended Reasons for Order and Order, filed in GlaxoSmithKline Inc. and Smithkline Beecham Corporation v. The Minister of Health and Pharmascience Inc., Court No. T-1871-01.	

Examiner Signature	/Kevin Weddington/ (03/20/2006)	Date Considered	
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